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10/696,709	10/30/2003	Edward W. Merrill	49931-0080	6478
90628 7590 12/14/2010 Massachusetts General Hospital The General Hospital Corporation Perkins Cole LLP 607 Fourteenth Street, NW Washington, DC 20005				
EXAMINER BERMAN, SUSAN W				
ART UNIT		PAPER NUMBER		
1765				
NOTIFICATION DATE		DELIVERY MODE		
12/14/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/696,709

Applicant(s)

MERRILL ET AL.

Examiner

/Susan W. Berman/

Art Unit

1765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-15-2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-140 is/are pending in the application.
- 4a) Of the above claim(s) 128-134 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-127 and 135-140 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

With respect to the amendment of claim 124, there is no discussion on page 19 of the specification that supports the amendment. There is a disclosure of pages 18 and on page 20 that UHMWPE is irradiated to crosslink the UHMWPE polymeric chains, and heating the irradiated UHMWPE above the melting point so that there are substantially no detectable free radicals, followed by cooling the heated UHMWPE to room temperature. The terminology "quenching residual free radicals" is not found; thus applicant does not have support in the specification for the claim language "quenching residual free radicals in the crosslinked UHMWPE preform by heating the irradiated UHMWPE".

Applicant is reminded that applicant is required to use claim language that finds support in the specification as filed. For example, applicant discloses irradiating to crosslink followed by heating to obtain a product having "substantially no detectable free radicals" so this terminology should be used in the claims instead of the phrase "quenching residual free radicals".

The rejection of claims 124-127 as being anticipated by Shalaby et al (5,824,411) is withdrawn. Shalaby et al disclose a method that comprises melting an UHMWPE "construct polymer-fiber" and irradiating the resulting composite with high energy radiation to sterilize and crosslink the composites of UHMWPE. However, Shalaby et al do not mention heating the irradiation crosslinked UHMWPE. Irradiation at room temperature is disclosed in Example 5. In response to applicant's arguments that Shalaby et al teach "low dose irradiation" or "sterilization irradiation", it is noted that Shalaby et al disclose high energy radiation, i.e., gamma, x-ray or electron beam radiation, and that the high energy radiation crosslinks the UHMWPE in column

6, lines 1-7. The irradiation taught by Shalaby et al to crosslink UHMWPE would be expected to at least reduce or eliminate any free radicals generated in the process.

Response to Arguments

Applicant's arguments filed 10/15/2010 have been fully considered but they are not persuasive.

Written description rejection:

Applicant's argument that applicant should not be required to limit the claims to specific embodiments disclosed in the Specification is not persuasive for the following reasons. Applicant discloses specific methods within the specification wherein each embodiment of a method describes materially different conditions with respect to times, temperatures and cooling that would be expected to result in different properties in the products produced, in the absence of evidence to the contrary. The disclosure does not suggest that any combination of the various disclosed limitations can be employed. The disclosure very specifically names different embodiments, i.e. "MIR", "CIR-SM", "WIR-SM", etc. For instance, a disclosure that UHMWPE is heated above the melting temperature for about 30 minutes to about 2 hours does not provide antecedent basis for claim language "pre-heating" UHMWPE to a "temperature greater than ambient temperature and less than the decomposition temperature of the UHMWPE for a period of time greater than 30 minutes" in claim 124.

With respect to claim language such as "ambient temperature" and "room temperature", since applicant uses "room temperature" in the specification, applicant should use "room temperature" in the claims. It is noted that the definition of "ambient temperature" as "the

temperature of the surroundings” does not show equivalence to “room temperature” which is an accepted term to denote a temperatures about 25⁰C , rather than any possible temperature of the “surroundings”.

With respect to the claim language "heating the irradiated UHMWPE" instead of the disclosed heating the irradiated UHMWPE to above the melting temperature of the UHMWPE, the phrase on page 14 pointed to by applicant supports the Examienr's position. What applicant discloses at page 14 is “free radicals can be eliminated”... “by heating the UHMWPE above the melting point”.

Applicant is not entitled to use claim terms found in US Patent 6,562,540 unless the same terms are also found in the instant specification. Applicant's claim language should be clearly supported by the language employed in the instant specification. If applicant intends to provoke an interference with the claims of US 6,562,540, applicant should first present claims containing language employed in the instant specification to write claim patentable to applicant and then describe why the patentable claim language describes a method equivalent to the patented method set forth in the claims of US '540.

Enablement rejection: This rejection is maintained for the reasons set forth herein above.

Obviousness rejection over Sun et al: Applicant argues that Sun et al do not disclose quenching free radicals formed upon irradiation. This argument is not persuasive for the following reasons. Sun et al specifically teach quenching free radicals remaining after irradiation by heat treatment followed by cooling (column 6, lines 48-51, and column 8, lines 11-20). No evidence to the contrary has been made of record. Applicant's claim language does not set forth

any specific steps for quenching free radicals that distinguish the instantly claimed method from the irradiation and heating steps taught by Sun et al. As set forth in the rejection herein below: Sun et al teach a method for forming a medical implant comprising annealing a medical implant and then radiation sterilizing the implant (column 5, lines 38-67, and column 6, lines 42-43). The irradiated implant is then further annealed to reduce free radicals (column 6, lines 48-51).

Double Patenting Rejections: The double patenting rejections of record are maintained.

Sequence of steps in the instant method claims:

Claim 124 now sets forth that the UHMWPE crosslinked by irradiation is heated so the step of heating must follow irradiation crosslinking. However, it is noted that the claim does not clearly set forth whether the step of irradiating to crosslink the UHMWPE takes place while the UHMWPE is at a elevated pre-heating temperature or after it has been cooled from the elevated pre-heating temperature.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 124-127 and 135-140 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Applicant is reminded that claim language should correspond to the description of the invention as originally filed.

With respect to claims 124-127, while applicant teaches pre-heating, the examiner has not found any disclosure of pre-heating “at a temperature greater than ambient temperature and less than the decomposition temperature” or “for a period of time greater than about 30 minutes”. What applicant discloses in the MIR method is heating above the melting temperature of UHMWPE for a time period “for about 30 minutes to about 2 hours” before irradiation and cooled to about 25⁰C after irradiation (pages 29-31). Alternatively, applicant discloses “pre-heating to a temperature below the melting temperature of the UHMWPE”, irradiation of the UHMWPE, followed by heating to a temperature above the melting temperature for a time period of about 0.5 minutes to about 24 hours, preferably about 1 hour to about 3 hours and most preferably for 2 hours so there are no detectable free radicals in the CIR or WIR method (pages 21-24). The examiner has not found any disclosure to support the instant claim recitation “**quenching** residual free radicals” after pre-heating and irradiation. What applicant discloses is a cooling step after irradiation and that the disclosed method provides “crosslinked UHMWPE having substantially no detectable free radicals”. The method disclosed for obtaining “crosslinked UHMWPE having substantially no detectable free radicals” requires heating the irradiated UHMWPE after irradiation **to above the melting temperature** of UHMWPE (pages 14, 20 and 21).

With respect to claim 125, the examiner has not found any disclosure of the recited cooling after the “**quenching** step to a **temperature below the melting temperature** of the polyethylene”. What is disclosed is cooling to room temperature after the step of heating

irradiated UHMWPE to above the melting temperature to provide “substantially no detectable free radicals”. See page 18.

With respect to claims 135-137, a step for obtaining “substantially no free radicals” disclosed in the specification on pages 14 and 21-22, wherein methods including the instantly claimed pre-heating are disclosed, i.e. “CIR” and “WIR” methods, requires heating the irradiated UHMWPE above the melting temperature of the UHMWPE. No disclosure has been found of the recited heating the irradiated UHMWPE preform to a temperature “above ambient temperature” to “quench” free radicals or of a “quenching step”. What is disclosed in the instant specification is a method wherein, subsequent to irradiation, the irradiated UHMWPE is heated above the melting temperature to provide a product having substantially no free radicals. The method disclosed should be clearly set forth in the instant claims.

Claims 124-127 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Heating irradiated UHMWPE above the melting temperature of the UHMWPE after irradiating UHMWPE to crosslink the UHMWPE is disclosed as being critical or essential to the practice of the invention, in order to obtain a product having “substantially no detectable free radicals”, but is not included in the claim(s). Therefore the claims, as written, are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The disclosure of obtaining “substantially no detectable free radicals” after pre-heating and irradiation in the instant specification requires heating above the melting temperature of UHMWPE.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 124-127 and 135-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al (5,414,049). Sun et al teach a method for forming a medical implant comprising annealing a medical implant and then radiation sterilizing the implant (column 5, lines 38-67, and column 6, lines 42-43). The irradiated implant is then further annealed to reduce free radicals (column 6, lines 48-51). The difference from the instantly claimed process is that Sun et al teach treating a formed implant rather than a preform. It would have been obvious to one skilled in the art at the time of the invention to apply the process steps taught by Sun et al to a polyethylene preform. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of imparting the desirable properties taught by Sun et al to a preform material since the polymeric material is polyethylene in the implant and in the preform.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-134 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. irradiating and heating a polyethylene article, are set forth in the claims of '440 and in the instant claims. The instantly claimed step of heating to a temperature less than the decomposition temperature is considered to encompass the melting step set forth in the claims of '440. Alternatively, the melting step set forth in the claims of '440 corresponds to the step of quenching free radicals set forth in the instant claims and the comprising language of the claims of '440 encompasses the pre-annealing step in the instant claims. With respect to claims 138-140, claim 134 of Application '440 recites irradiation with a dose from about 5 to about 100 Mrad, thus encompassing the instantly claimed 4 to 30 Mrads. With respect to claims 126 and 127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124, 126-129

and 135-137 of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. With respect to claims 126-127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209. With respect to claims 135-137, the comprising language of the claims of application '209 encompasses a step of quenching free radicals after irradiation. With respect to claims 138-140, the claims of Application '209 recite a radiation dose greater than 1 Mrad and a greater than 20 Mrad.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. The step of heating above the melting temperature set forth in the claims of '362 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 114 and 124-129 of copending Application No. 10/901089. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the heated UHMWPE are set forth in the claims of '089 and in the instant claims. The step of heating above the melting temperature set forth in the claims of '089 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
12/08/2010

/Susan W Berman/
Primary Examiner
Art Unit 1765